

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**Applicant(s):** B. Lauren Charous

**Examiner:** Unassigned

**Serial No:** To be assigned

**Art Unit:** Unassigned

**Filed:** Herewith

**Docket:** 15078Z

**For:** A METHOD FOR TREATING  
INFLAMMATORY BOWEL DISEASE

**Dated:** February 13, 2004

Commissioner for Patents  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following disclosures, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

1. U.S. Patent No. 4,181,725 to Voorhees, et al., issued January 1, 1980;
2. Barnes, Peter J., "Asthma Therapy with Aerosols: Clinical Relevance for the Next Decade", Journal of Aerosol Medicine, Vol. 9, No. 1, 1996, pp. 131-141;
3. Busse, William W., et al., "Treatment Regimen and Side Effects of Treatment Measures", Am. J. Respir. Crit. Care Med., Vol. 149, pp. S44-S50, 1994;

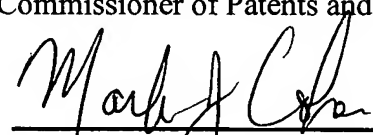
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I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Alexandria, VA 22313-1450.

Dated: February 13, 2004

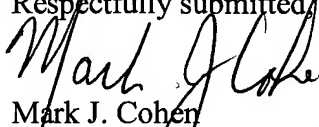
  
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Mark J. Cohen

4. Charous, Lauren B., "Open study of hydroxychloroquine in the treatment of severe symptomatic or corticosteroid-dependent asthma", Annals. of Allergy, Vol. 65, July, 1990, pp. 53-58;
5. Charous, Lauren B., et al., "Hydroxychloroquine improves airflow and lowers circulating IgE levels in subjects with moderate symptomatic asthma", J. Allergy Clin. Immunol., Vol. 102, No. 2, 1998, pp. 198-203;
6. Charous, Lauren B., "Effectiveness of Long-Term Treatment of Severe Asthma with Hydroxychloroquine (HCQ)", Annals. of the New York Academy of Sciences, Vol. 629, pp. 432-433;
7. Charous, Lauren B., et al., "Double-blind Trial of Hydroxychloroquine (HCQ) as Anti Allergic Anti-Asthmatic Therapy", J. Allergy Clin. Immunol., January 1997;
8. Charous, Lauren B., "Long-Term Treatment of Severe Asthma with Hydroxychloroquine", Annals of Allergy, Vol. 68, No. 1, p. 80, 1992;
9. Charous, Lauren B., "Double-blind Trial of Hydroxychloroquine (HCQ) As Anti-Allergic Anti-Asthmatic Therapy", J. Allergy Clin. Immunol., January 1997, p. S268;
10. Cockcroft, D.W., "Therapy for airway inflammation in asthma", J. Allergy Clin. Immunol., May 1991, Vol. 87, No. 5. pp. 914-919;
11. Fox, Robert I., et al., "Treatment of Primary Sjogren's Syndrome with Hydroxychloroquine", The American Journal of Medicine, Vol. 85, 1998, p. 62-67;
12. Goldstein, Jay A., "Hydroxychloroquine for Asthma", Am. Rev. Res. Diseases, 128(6):1100-1101;
13. Landwehr, Lawrence P., et al., "Management of Steroid-Resistant Asthma", Clin. Immunother., 4(2) 1995, pp. 124-137;
14. Ledford, Dennis K., "Alternative Treatments for Severe, Chronic Asthma", Allergy Proc., January-February 1993, Vol. 14, No. 1, pp. 23-30;
15. Ledford, Dennis K., "Treatment of Steroid-Resistant Asthma", Immunology and Allergy Clinics of North America, Vol. 16, No. 4, November 1996, pp. 777-796;
16. Moss, Richard B., "Alternative Pharmacotherapies for Steroid-Dependent Asthma", Chest, Vol. 107, No. 3, March 1995, pp. 817-825;

17. Ornstein, Matthew H., et al., "The Anti-Inflammatory and Antiviral Effects of Hydroxy-Chloroquine (HCQ) in 2 Patients with Aids and Active Inflammatory Arthritis", Arthritis & Rheumatism, Vol. 38, No. 9, p. S198;
18. Roberts, J.A., et al., "Effect of Hydroxychloroquine in Chronic Steroid Dependent Asthma", J. Allergy Clin. Immune, 1986, Vol. 77, No. 1, Part 2, p. 151;
19. Roberts, J.A., et al., "Hydroxychloroquine in Steroid Dependent Asthma", Pulmonary Pharmacology, 1998; p. 59-61;
20. Seggey, J.S., et al., "Inhibition of IL-4-Driven IgE Synthesis by Peripheral Blood Lymphocytes (PBL) in vitro with Hydroxychloroquine (HCQ)", Allergic Disease IgE, No. 343, p. 62A;
21. Sherman, et al., "Short-Term Effects of Hydroxychloroquine (HCQ) on IgE Levels and Obstructive Airways Disease", J. Allergy Clin. Immunol., January 1992, No. 567, p. 286; and
22. Sorkness, Christine, et al., "Alternatives to Corticosteroids in the Treatment of Asthma", Immunology and Allergy Clinics of North America, Vol. 13, No. 4, November 1993, p. 917-938.

Pursuant to 37 C.F.R. §1.98(d), copies of the above listed references are not provided, as references 1-22 were previously submitted to the Examiner and in connection with parent case, U.S. Serial Number 10/293,769 filed on November 12, 2000.

Inasmuch as this Information Disclosure Statement is being filed prior to the issuance of any action on the merits, no fee or certification is due.

Respectfully submitted,  
  
Mark J. Cohen  
Registration No.: 32,211

Scully, Scott, Murphy & Presser  
400 Garden City Plaza  
Garden City, New York 11530  
(516) 742-4343  
MJC:lf

Form PTO-1449 (REV. 7-80)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Atty. Docket No. 15078Z	Serial No. Unassigned
<b>LIST OF PRIOR ART CITED BY APPLICANT</b>  (Use several sheets if necessary)		Applicant B. Lauren Charous	
		Filing Date Herewith	Group Unassigned

**U.S. PATENT DOCUMENTS**

EXAMINER INITIAL*		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (if appropriate)
	AA	4,181,725	1/1/80	Voorhees, et al.			
	AB						
	AC						
	AD						
	AE						
	AF						
	AG						
	AH						
	AI						

**FOREIGN PATENT DOCUMENTS**

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO
	AK							
	AL							

**OTHER PRIOR ART (Including Author, Title, Date, Pertinent Pages, Etc.)**

AM	Barnes, Peter J., "Asthma Therapy with Aerosols: Clinical Relevance for the Next Decade", <u>Journal of Aerosol Medicine</u> , Vol. 9, No. 1, 1996, pp. 131-141.
AN	Busse, William W., et al., "Treatment Regimen and Side Effects of Treatment Measures", <u>Am. J. Respir. Crit. Care Med.</u> , Vol. 149, pp. S44-S50, 1994.
AO	Charous, Lauren B., "Open study of hydroxychloroquine in the treatment of severe symptomatic or corticosteroid-dependent asthma", <u>Annals. of Allergy</u> , Vol. 65, July, 1990, pp. 53-58.
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AV	Cockcroft, D.W., "Therapy for airway inflammation in asthma", <u>J. Allergy Clin. Immunol.</u> , May 1991, Vol. 87, No. 5. pp. 914-919.

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Form PTO-1449  
(REV. 7-80)U.S. DEPARTMENT OF COMMERCE  
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15078ZSerial No.  
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(Use several sheets if necessary)

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	AN	Sherman, et al., "Short-Term Effects of Hydroxychloroquine (HCQ) on IgE Levels and Obstructive Airways Disease", <u>J. Allergy Clin. Immunol.</u> , January 1992, No. 567, p. 286.						
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